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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,795	08/19/2003	Frederic J. DeSauvage	P5026R1	6007
9157	7590	09/20/2007	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			YAO, LEI	
		ART UNIT	PAPER NUMBER	
		1642		
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		09/20/2007		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/643,795	DESAUVAGE ET AL.
	Examiner Lei Yao, Ph.D.	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 July 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 16-18 is/are pending in the application.  
 4a) Of the above claim(s) 18 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 16 and 17 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

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**Request for Continued Examination**

The request filed on 17/20/2007 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10643795 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 16-18 are pending. Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claims.

Claims 16 and 17 are examined on the merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Gish et al., (WO02/30268, published date 4/18/02) as evidenced by sequence search (provided in previous office action).

Claims are drawn to a method of diagnosing the presence of a prostate tumor in a mammal comprising determining that the level of expression of a gene encoding the polypeptide shown as SEQ ID NO: 123 in a test sample of prostate tissue cells obtained from said mammal is higher than the expression level in a control sample of known normal prostate tissue cells, wherein said a higher level of expression is indicative of the presence of a prostate tumor in the mammal from which the test sample

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was obtained (claim 16), wherein the step of determining the level of expression of said gene comprises employing an oligonucleotide in an *in situ* hybridization or RT-PCR analysis (claim 17).

Gish et al., disclose a method of diagnosing a prostate cancer by detecting a prostate cancer-associated transcript (mRNA) in a cell from a patient comprising determining a nucleic acid encoding a polypeptide, which is 99.6% identical to the amino acid sequence of SEQ ID NO: 123, different at first 4 amino acids (see sequence search; page 322-323 and 139, protein sequence, SEQ ID NO: 53 having accession no: AA431407 or unigene ID No, Hs.98802, provided in previous office action). Gish et al., disclose the method comprising contacting a biological sample from a prostate patient with a polynucleotide probe that selectively hybridizes to the sequence (page 3). Gish et al., further disclose that the nucleic acid comprising mRNA expressed in prostate cancer sample is detected by *in situ* hybridization or PCR (page 59, 61, and 91-97, example 1). Gish et al., also disclose that expressing the specific prostate cancer gene in the prostate tumor tissue is 33.6 times higher (RI=33.6) compared to the normal prostate tissue (Table 4, page 139, line 3).

Since claimed method is not drawn to a specific oligonucleotide as primers or a probe for the *in situ* hybridization or RT-PCR, the method disclosed by Gish et al., anticipates the claimed method of diagnosing the presence of a prostate tumor comprising determining the higher levels of expression of a gene encoding the polypeptide shown as SEQ IDNO: 123 by an *in situ* hybridization or RT-PCR.

#### Response to Applicant's Argument.

The response filed 7/20/2007 has been carefully considered but is deemed not to be persuasive.

The response states:

Gish is not an anticipatory reference because it does not enable that which it is asserted to anticipate. As currently amended, claim 1 (applicant may mean claim 16) includes the step of determining that the level of expression of a gene encoding the polypeptide shown as SEQ ID NO: 123 in a test sample of prostate tissue cells obtained from said mammal is higher than the expression level in a control sample of known normal prostate tissue cells, wherein said higher level of expression is indicative of the presence of a prostate tumor in the mammal from which the test sample was obtained. The present invention concerns a determination that a gene exhibits a higher level of expression in a test sample from a subject than in a control sample, which indicates the presence of a prostate tumor in the subject. Gish does not provide an enabling disclosure for the detection of an elevated level of gene expression as an indicator of prostate cancer.

In response to this argument, Gish et al., not only disclose the method step in entire disclosure by stating the method comprising determining the expression of gene in first tissue (prostate tissue) and comparing the expression gene from second (normal) tissue (e.g page 7, line 12+), but also on table 4, page 139, Gish et al., specifically teach the expression of prostate cancer gene AA431407 (SEQ ID NO: 53) is 33 times higher in the prostate tumor tissue than the normal prostate tissue. Gish et al., also teach the differential expression indicates that the first individual has a disorder associated with prostate cancer (page 7, line 16-17).

Since Gish et al., teach the active method steps, and the preamble of the invention, the teaching of Gish et al., is enabled. Since Gish et al., teach every element of claimed method, it, therefore, anticipate claimed method. Thus, Applicant's argument has not been found persuasive, and the rejection is maintained.

2. Claims 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Gish et al., (US PG Pub. 2007/0014801, effective filing date, Jan 2001) as evidenced by sequence search result in database rnpm.

Claims 16 and 17 are set forth above.

Gish et al., disclose a method of diagnosing a prostate cancer by detecting a prostate cancer-associated transcript (mRNA) in a cell from a patient comprising determining a nucleic acid encoding a polypeptide, which is 100% identical to the amino acid sequence of SEQ ID NO: 123 from amino acids 5-1127 (different at first 4 amino acids, see sequence search; SEQ ID NO: 105 having accession no: AI460004). Gish et al., disclose a method of detecting a prostate cancer-associated transcript in a cell from a patient, the method comprising contacting a biological sample from the patient with a polynucleotide that selectively hybridizes to a sequence (paragraph 0008). Gish et al., further disclose that the nucleic acid comprising mRNA expressed in prostate cancer sample is detected by *in situ* hybridization or PCR (paragraph 0093 and 0210). Gish et al., also disclose that expressing the specific

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prostate cancer gene (SEQ ID NO: 105, PEU5, having accession no: AI460004) in the prostate tumor tissue is up-regulated eight times compared to the normal prostate tissue (Table 3, page 127, line 3).

Since claimed method is not drawn to a specific oligonucleotide as primers or a probe for in situ hybridization or RT-PCR, the method disclosed by Gish et al., anticipates the claimed method of diagnosing the presence of a prostate tumor comprising determining the higher levels of expression of a gene encoding the polypeptide shown as SEQ IDNO: 123 by an in situ hybridization or RT-PCR.

### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,  
Examiner  
Art Unit 1642

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